

There are also several additional endpoints which the SAB recommended for evaluation and consideration during review of the first draft of this blueprint. Additional endpoints suggested for consideration which we plan to include in sensitivity analysis – but not in the primary quantitative benefit results – include (a) PM-related infant mortality and (b) ozone-related mortality.

The June 2001 draft analytical blueprint indicated EPA's intent to exclude PM-related post-neonatal infant mortality based on concerns expressed during a 1999 SAB review that the single available study (Woodruff et al., 1997) did not provide evidence adequate to support inclusion of this endpoint in the previous study.¹ However, in their September 2001 report reviewing the June 2001 draft blueprint for the current study (EPA-SAB-COUNCIL-ADV-004), the SAB cited new evidence reporting significant PM-related infant mortality including an eight-city study by Kaiser et al. (2001), Ha et al. (2001) in Seoul, and two others studies that relate PM₁₀ to birthweight. Additional research is needed to explore these studies and how they might be incorporated into the second prospective study. We will provide the estimated effect of PM exposure on premature mortality in post neo-natal infants to show the specific impacts on an especially susceptible subpopulation. At this time, however, the estimates are not meant to be additive to the primary estimates of mortality.

We exclude ozone-related mortality from the primary analysis and include it as a sensitivity analysis because of concerns about double-counting the impact of PM and ozone on premature mortality *as well as questions about ozone causality raised by the SAB*. Additional research is needed to provide separate estimates of the effects for PM and ozone. To be conservative, we therefore include only the effect of PM on premature mortality in the primary analysis. We plan to explicitly address the uncertainty surrounding this endpoint, however, in our quantitative evaluations of uncertainty, as described in Chapter 9, and seek SAB input on the appropriate treatment for this endpoint.

Baseline Incidence

The baseline incidences for health outcomes we will use in the second prospective analysis are selected and adapted to match the specific populations studied. For example, we will use age- and county-specific baseline total mortality rates in the estimation of PM-related premature mortality. County-level incidence rates are not available for other endpoints. We will use national incidence rates whenever possible, because these data are most applicable to a national assessment of benefits. However, for some studies, the only available incidence information comes from the studies themselves; in these cases, incidence in the study population is assumed to represent typical incidence at the national level. Sources of baseline incidence rates are reported in Exhibit 6-2.

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¹ “3.5.2 PM Neonatal Mortality. HEES recommends that PM-related infant mortality data not be included in the analysis, without further supporting peer-reviewed published reports. The Agency must have an adequate data base (i.e., at least two or more peer-reviewed published reports) in order to derive a C-R coefficient. The current information does not support the use of neonatal mortality. Thus, neonatal mortality should not be included in the Prospective Study.” (EPA-SAB-COUNCIL-DV-99-005, page 12).